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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,475

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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1639

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/694,475

Applicant(s)

TEREBA ET AL.

Examiner

CHRISTOPHER M. GROSS

Art Unit

1639

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-82 is/are pending in the application.
- 4a) Of the above claim(s) 55-57, 59 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-54, 58, 60-70, 72-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Responsive to communications entered 10/31/2007; 8/14/2008. Claims 44-82 are pending. Claims 55-57,59,71 are withdrawn. Claims 44-54,58,60-70,72-82 are examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election without traverse of: "forensic sample " for the species of sample, in the reply filed on 8/14/2008 is acknowledged.

The species of plasmid for the species of DNA has been fortuitously found in the prior art thus, in the interest of compact prosecution, claim 52 is hereby rejoined.

Claims 55-57,59,71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of sample, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/14/2008.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

The instant application, filed 12/5/2003 is a DIV of 09/377,986 filed 8/20/1999 (now PAT 6673631) which is a CIP of 08/785097 filed 1/21/1997 (now PAT 6027945). Nevertheless, isolating a consistent amount of DNA from each sample, such as set forth in claim 44 is not disclosed in the earliest application (PAT 6027945).

Therefore 8/20/1999 is the date for the purposes of prior art concerning claims 44-82.

Response to Arguments

On p 8 of remarks entered 10/31/2007, applicant admits that isolating a consistent amount of DNA from each sample is not disclosed in US Patent 6027945, thus 8/20/1999 remains the date for the purposes of prior art.

Withdrawn Rejection(s)

The rejection of claim 68 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention is hereby withdrawn in view of applicant's amendments.

The rejection of claims 44-47,49-52,54,55,58-65,68,69-74 under 35 U.S.C. 102(b) as being anticipated by **Smith et al** (WO 98/31840 – IDS entry 1/27/2003) is hereby withdrawn in view of applicant's amendments.

The rejection of claim 44-52,54,55,58,59-68 under 35 U.S.C. 103(a) as being unpatentable over **Kleiber et al** (WO 96/41811 – IDS entry 1/8/2007) in view of **Huber et al** (1993 Nucleic Acids Research 21:1061-1066) as evidenced by *Volgelstein et al* (1979 PNAS 615-619 – IDS entry 10/27/2003) is hereby withdrawn in view of applicant's amendments.

Maintained Claim Rejection(s) - 35 USC § 102

Claims 66-67 are rejected under 35 U.S.C. 102(b) as being anticipated by **Smith et al** (WO 98/31840 – IDS entry 1/27/2003).

Response to Arguments

On p 9 of remarks entered 10/31/2007, applicant argues that WO 98/31840 has an identical disclosure to application 08/785097 (now PAT 6027945), thus if priority is not afforded the '097 application, then Smith et al can not be said to anticipate the claimed invention.

In this regard, the examiner submits that the requirement for anticipation under 35 USC 102 differs from that of possession under 35 USC 112 first paragraph.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species, by actual reduction to

practice, reduction to drawings, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly* 119 F.3d at 1568. 43 USPQ2d at 1406.

Here, applicant claims a broad genus of contacting any type of DNA with a discrete amount of any type of silica-containing support in excess of the binding capacity of the silica-containing solid support capable of reversible binding to isolate a consistent amount of DNA from multiple samples, yet the disclosure of application 08/785097 (and WO 98/31840 to Smith et al) only discloses one species of DNA (a plasmid) capable of reversible binding to magnetic Controlled Pore Glass (CPG) so as to isolate a consistent amount of DNA from multiple samples, as illustrated in the titration curve in figure 1 and recovery in figure 2 and detailed in the last office action.

The examiner submits that said magnetic CPG plus plasmid DNA does not constitute a representative number of species and in this regard, accordingly the court has stated, *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Here, application 08/785097 does not clearly allow persons of ordinary skill in the art to recognize the breadth now claimed.

In conclusion, the magnetic CPG plus plasmid DNA of Smith et al constitutes prior art as a species anticipating a genus under 35 USC 102, however the disclosure of Smith et al does not provide adequate support under 35 USC 112 first paragraph for the genus set forth in present claims 66-67.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44,45,50,53,66,67,82 are rejected under 35 U.S.C. 102(b) as being anticipated by **Melzak et al** (1996 J. Colloid and Interface Science 181:635-644) as evidenced by information available at <http://seq.yeastgenome.org/>

The claimed subject matter per claim 44 is drawn to a method for isolating a defined and consistent amount of DNA from multiple samples comprising:

- (a) selecting a defined amount of DNA to be isolated from the samples;
- (b) choosing a discrete amount of a silica-containing solid support necessary to isolate the defined amount of DNA from each sample;
- (c) contacting each sample with the discrete amount of the silica-containing solid support, each sample comprising DNA in excess of the binding capacity of the discrete amount of silica-containing solid support, under conditions that allow reversible binding of the defined amount of DNA to the solid support; and
- (d) separating each sample from the support to isolate a defined and consistent amount of DNA from each sample.

Claims 45,50,53,65,67 and 82 represent variations thereof.

Melzak et al teach, throughout the document and especially the title and abstract, a study of the dominant driving forces involved in DNA adsorption to silica in perchlorate solutions.

Melzak et al teach in figure 3b, a DNA titration of silica which shows closed circle data points (i.e. multiple pUC18 samples) forming a saturation curve. Said saturation occurs at and above approximately 4 ug/mL DNA.

On p 637, fourth full paragraph, Melzak et al teach measuring said silica surface area as $5.6 \text{ m}^2/\text{g}$, by BET adsorption, reading on claim 44b. Said saturation of 380 ug DNA per m^2 on said silica per figure 3b of Melzak et al means said silica provides 2090 ug DNA (5.6×380) bound per g silica.

Notably, in accordance with the open circles in figure 3b of Melzak et al, each of said pUC18 DNA samples are eluted completely (i.e. quantitatively reversibly desorbed), therein each of said closed circle data points represents selecting a defined amount of DNA to be isolated, as set forth in claim 44a.

Past said saturation point, the DNA samples are introduced to the silica in excess of the silica binding capacity, reading on claims 44c and 66a and said quantitative reversible desorption of the full capacity of the silica mentioned above reads on claims 44d, 45, and, absent evidence to the contrary, said eluted DNA may be used in a molecular biology procedure, as set forth in claim 66b. As would be expected for quantitative desorption, the variability of the eluted DNA past the saturation point appears minimal and in the range of claim 82.

Said perchlorate is taken as the chaotropic salt of claim 50. The conditions shown in the legend to figure 3 of Melzak et al indicate said perchlorate is 6 molar, reading on claim 65.

Said pUC18 reads on the plasmid DNA of claim 53 and has a known sequence, available at http://seq.yeastgenome.org/vectordb/vector_descrip/COMPLETE/PUC18.SEQ.html, which includes short tandem repeats, reading on claims 67.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44,45,50,53,65,67,82 and 46-49,51-52,54,58,60-64,68,77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Melzak et al** (1996 J. Colloid and Interface Science 181:635-644) in view of **Kleiber et al** (WO 96/41811 – IDS entry 1/8/2007).

Melzak et al is relied on as above.

Melzak et al do not teach: magnetic particles, such as set forth in claims 46-49; guanidine thiocyanate (claim 51); genomic DNA (claim 52); further analysis (claim 54); forensic samples (claim 58); heating samples from 60 degrees to 100 degrees (claim 60); sequencing (claim 61); washing with an alcohol and salt (claims 62-63); elution with water (claim 64); Combined DNA Index System Loci (claim 68); DNA amplification (claim 77); sequencing (claim 78); hybridization (claim 79); elution in a discrete volume such that the eluted DNA is from about 0.5 to about 5.0 ng/ul (claims 80-81).

Kleiber et al teach, throughout the document and especially the abstract porous and poreless boro/aluminio/zirconio-silicate magnetic particles useful for DNA isolation. Kleiber et al teach in figure 2 and example 3, separating DNA from said magnetic particles to isolate a defined amount of DNA from each type of particle. For instance, on p 19 first paragraph, Kleiber et al indicate said DNA was eluted from magnetic particle with 3 x 200 microliters, reading on claim 80, and sample GMP/2 on the table on p 21 indicates an ultimate yield of $1.7 \text{ ug} = 2.8 \text{ ng/ul}$ ($1.7/600 \times 1000$), in the range of claim 81.

Said porous and poreless magnetic particles of Kleiber et al are taken as the siliceous-oxide magnetic particles (elected species) of claims 46,47,48 and 49.

Kleiber et al teach chaotropic salts including guanidine thiocyanate on p 9, second paragraph, line 14, reading on claims 50 and 51.

Kleiber et al teach in example 3, the use of blood as a genomic DNA sample, reading on claim 52 (elected species). Said blood is subsequently analyzed in example 3 of Kleiber et al, as set forth in claim 54.

Said blood is taken as type of forensic sample, such as set forth in claim 58 (elected species).

Said blood inherently comprises Combined DNA Index System Loci, as set forth in claim 68.

Said blood is contacted with 6 Molar guanidine HCl, a chaotropic salt at 70 degrees C on p 18, according to Kleiber et al in the second paragraph under Nucleic Acid Isolation, in the range of claims 60 and 65.

Kleiber et al teach on p 19, line 4 washing of the magnetic particles with ethanol/water, reading on claims 62 and 63.

Kleiber et al teach elution with water in the second paragraph on p 11, last line, therein reading on claim 64.

Kleiber et al teach the magnetic particles may be used in concert with molecular biology procedures including amplification, sequencing and hybridization on p 12 first full paragraph, reading on claims 61, 77, 78 and 79.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to apply the procedure of Melzak et al for discerning the dominant driving forces involved in DNA-silica interactions toward the

porous and poreless boro/aluminio/zirconio-silicate magnetic particles according to Kleiber et al.

One of ordinary skill in the art would have been motivated to apply the procedure of Melzak et al for discerning the dominant driving forces involved in DNA adsorption toward the porous and poreless boro/aluminio/zirconio-silicate magnetic particles according to Klieber et al because a better understanding of DNA-SiO_x interactions would speed development of new tools for DNA diagnostics, such as micromachines, which represents a critical area of research for international competitiveness, as noted by Melzak et al in the second paragraph on p 635.

One of ordinary skill in the art would have had a reasonable expectation of success in applying the procedure for measuring the dominant driving forces involved in DNA-silica interactions described by Melzak et al toward the porous and poreless boro/aluminio/zirconio-silicate magnetic particles according to Kleiber et al because both references concern silica adsorption and desorption of DNA. Thus the magnetic particles of Kleiber et al lie well within the scope of material suitable for analysis in the manner of Melzak et al.

In conclusion, the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Claims 69-70,72-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Melzak et al** (1996 J. Colloid and Interface Science 181:635-644) in view of

Kleiber et al (WO 96/41811 – IDS entry 1/8/2007) as applied to claims

44,45,50,53,65,67,82 and 46-49,51-52,54,58,60-64,68,77-81 above, and further in view of **Ryder et al** (US Patent 5639599).

Melzak et al in view of Kleiber et al is relied on as above.

Melzak et al in view of Kleiber et al do not teach a kit, as set forth in claims 69-70,72-76.

Ryder et al teach, throughout the document and especially the abstract, and column 1, lines 14-16, 37-40 kits containing ferric iron complexing agents for nucleic acid isolation.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to include the reagents used by Melzak et al in view of Kleiber et al with the kit such as described by Ryder et al.

One of ordinary skill in the art would have been motivated to include the reagents used by Melzak et al in view of Kleiber et al with the kit such as described by Ryder et al because Ferric ions (Fe^{+++}) interfere with downstream applications, such as amplification, as noted by Ryder et al in column 2 lines 15-16.

One of ordinary skill in the art would have had a reasonable expectation of success in utilizing the iron complexing reagent kit in concert with the reagents used by Melzak et al in view of Kleiber et al because Ryder et al envisions an embodiment including silica in claim 21. Furthermore, all three references concern nucleic acid isolation, thus the kit including iron complexing agents lie well within the scope of technology according to Melzak et al in view of Kleiber et al.

In conclusion, the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

New Claim Rejection(s) – 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76 and 81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns “new matter.”

New claim 76 is drawn to a kit and applicant points to the passage at p 22 lines 30-32 as providing support. Said passage does not mention kits.

New claim 81 is drawn to DNA concentrations from about 0.5 ng/ul to about 5.0 ng/ul and applicant points to the passages at p 25 lines 33-39 and p 7 lines 2-4 as providing support. Said passage does not mention the volume, thus does not provide adequate support for said DNA concentrations.

The specification as originally filed provided no implicit or explicit support for the kit as set forth in claim 76 of the concentration range of claim 81.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

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